DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

# Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS)

1. Technology Name: ***INFUSE™ Bone Graft (Large Kit)***

2. Manufacturer Name: ***Medtronic Sofamor Danek, Inc***

3. Trade Brand of Technology: INFUSE™ Bone Graft (Large Kit)

4. Brief Description of Service or Device:

   ***INFUSE™ Bone Graft consists of recombinant human bone morphogenetic protein-2 (rhBMP-2), which induces bone formation in the fracture site, and an absorbable collagen sponge (ACS) matrix, which serves as the carrier for the rhBMP-2 at the fracture site. Use of INFUSE™ Bone Graft significantly improves union of tibial fractures.***

## New Criteria

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

   ***December 2003***

6. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

   a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

      ***84.52 - Insertion of recombinant human bone morphogenetic protein, is the code used to identify cases using INFUSE™ Bone Graft. This code is always***

**(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_03_application.pdf)**
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***used with another code, such as 79.36 – Reduction, fracture, open, internal fixation, tibia and fibula.***

b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/paymentsystems/icd9 for more information.)

7. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://cms.hhs.gov/providers/hopps/apc.asp for more information.)

***No***

## Cost Criteria

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of 75 percent of one standard deviation above the average charges for the DRG(s) to which the technology or service is assigned.

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

***The anticipated standardized charge for those cases mapping to DRG 218 is $29,370.***
***The anticipated standardized charge for those cases mapping to DRG 219 is $24,808.***

9. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology).

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***The cost of the new technology is $4,900 for the large INFUSE™ Bone Graft kit for each patient. There are no other additional costs associated with this technology.***

10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

***DRG 218 Lower Extremity and Humerus Procedures Except Hip, Foot and Femur, Age Greater than 17 with CC***

***DRG 219 Lower Extremity and Humerus Procedures Except Hip, Foot and Femur, Age Greater than 17 without CC***

***DRG 220 Lower Extremity and Humerus Procedures Except Hip, Foot and Femur, Age 0-17***
***(There were no open tibial fracture cases in the MedPAR 2002 database for this DRG)***

11. What is the anticipated volume of Medicare cases involving use of this technology (by DRG)?

***We believe INFUSE™ Bone Graft will be used in approximately 555 cases during FY05. The expected expenditure for CMS would be $1.4 Million.***

## Clinical Improvement

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

    a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

***Open fractures of the tibial shaft are particularly prone to delayed union despite advances in fracture stabilization. Orthopedic literature reports delayed union of open tibial shaft fracture ranging from 16% to 60% for less***

***severe fractures, and from 43% to 100% for more severe fractures. Delayed union and secondary interventions to promote union increase morbidity and decrease quality of life of a high percentage of patients who sustain an open tibial shaft fracture.***

***INFUSE™ Bone Graft is an advance in medical technology that represents a substantial clinical improvement over the standard management of tibial shaft fracture by greatly enhancing the induction of new bone in the fracture site. The most compelling support for this breakthrough technology comes from a prospective, controlled study involving 49 trauma centers in 11 countries. This study enrolled 450 patients who had sustained an open tibial shaft fracture that would be treated by intramedullary nail fixation and soft tissue management (standard of care). These patients were randomly assigned, blinded to whether or not they would also receive rhBMP-2/ACS treatment. Secondary interventions were necessary in 46% of the patients in the control group and 26% of the patients in the 1.50 mg/ml rhBMP-2 group -- Notably, the rhBMP-2 group had 44% fewer patients who required secondary interventions than the control group. Also when compared to the control group, the rhBMP-2 group had a significantly greater percentage of patients with soft tissue healing at 6 weeks, a significantly higher percentage of patients with fracture healing at 6 months, a significantly lower percentage of patients with infections in the fracture site, and a significantly lower percentage of patients with hardware failures.***

***In summary, INFUSE™ Bone Graft substantially improves the standard management of open tibial shaft fractures by inducing fracture healing, thereby reducing the need for secondary interventions to promote healing.***

b. List of published peer-review articles relevant to the new service or technology.

***McDonough Emily. BMP-2 Enhanced Healing In Open Tibia Fractures. Orthopedics Today; August 2003; 55***

***Govender S, Csimma C, Genant HK, Valentin-Opran V, for the BMP-2 Evaluation in Surgery for Tibial Fracture (BESTT) Study Group. Recombinant human bone morphogenetic protein-2 for treatment of open tibial fractures: A prospective, controlled, randomized study of four hundred and fifty patients. J Bone Joint Surg 2002;84A:2124-2134.***

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*Valentin-Opran A, Wozney J, Csimma C, et al. Clinical evaluation of recombinant bone morphogenetic protein-2. Clin Orthop 2002;395:110-120.*

*Ridell Gerald E., Valentin-Opran Alexandre. Preliminary Report: New Technology Clinical Evaluation of rhBMP-2/ACS in Orthopedic Trauma: A Progress Report. Orthopedics July 1999;22:664-665.*

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